K02 3476

JAN 0 7 2003

B. Administrative Information

1. 510(k) Summary of Safety and Effectiveness

Date Prepared

October 8, 2002

Submitter's Information

Universal PACS, Inc.
127 Albert Hart Drive
Baton Rouge, LA 70803
Phone: (225) 766-9381

Contact Person

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CEO, Universal PACS, Inc.
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Device

Trade Name:	UniPACS Workstation
Common Name:	Picture Archiving and Communications System
Classification Name:	PACS (per 21 CFR 892.2050), LLZ, Class II

Substantially Equivalent To

eFilm Workstation
(k012211, see also k020995))
eFilm Medical Inc.
500 University Ave, Suite 300
Toronto, Ontario
Canada M5G 1V7
www.efilm.ca

Device Description

The UniPACS Workstation is a Windows-based software application acting as stand alone Picture Archiving and Communications System (PACS). It may be marketed as software only, as well as packaged with standard "off-the-shelf" PC hardware.

The comprehensive set of tools provided in this software allows the physician to review, interpret, manipulate, print and visualize medical image data stored in DICOM format. The networking component of the product allows the physician to exchange image data with any other DICOM-compatible or FTP-compatible server over a standard TCP/IP network. The web component of the product displays workstation images in the web-browser interface, for remote review and reporting.

The device does not contain the patient, nor does it control any life sustaining devices.

Indications for Use

UniPACS Workstation software is intended to be used as a fully-functional, PC-based PACS, to review, interpret, manipulate, network, print and visualize medical multi-modality image data in DICOM format. When interpreted by a trained physician, reviewed images can be used as an element for diagnosis.

Typical users of this system are trained professionals, including but not limited to physicians, nurses and technicians.

Technological Comparison to Predicate Device

The proposed (UniPACS) and predicate (eFilm) devices are both software programs that can be used for manipulation of DICOM-compliant images on PC hardware. The proposed and predicate software can be operated from a personal computer, and provide a standard set of features with respect to image processing, storage and networking. The detailed feature comparison between the UniPACS Workstation and the eFilm Workstation demonstrates that, except a few minor, unimportant differences, the UniPACS Workstation provides the users with functionality, equivalent to that of the eFilm Workstation predicate device. This is a strong proof that the UniPACS and eFilm PACS Workstations are substantially equivalent.

Conclusion

Universal PACS Inc. considers the UniPACS Workstation to be substantially equivalent to the eFilm Workstation (k012211) device. The 510(k) Premarket Notification for the UniPACS Workstation contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

The UniPACS Workstation PACS software will be manufactured in accordance with the voluntary standards and development techniques listed in the submission. The software does not result in any new potential safety risks and performs as stated in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

Mr. John M. Tyler
CEO
Universal PACS, Inc.
127 Albert Hart Drive
BATON ROUGE LA 70803

Re: K023476
Trade/Device Name: UniPACS Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 8, 2002
Received: October 16, 2002

Dear Mr. Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

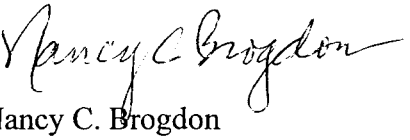
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. FDA Statement of Indications for Use

510(k) Number (if known) K02 3476

Device Name: UniPACS Workstation

Indications for Use:

UniPACS Workstation software is intended to be used as a fully-functional, PC-based PACS software application, to review, interpret, manipulate, network, print and visualize medical multi-modality image data in DICOM format. When interpreted by a trained physician, reviewed images can be used as an element for diagnosis.

Typical users of this system are trained professionals, including but not limited to physicians, nurses and technicians.

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Segarra

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023476